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IP/AU00/00389



10/24/01

REC'D 23 MAY 2000

WIPO

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AU 00/00389

Patent Office
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I, KAY WARD, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ 0029 for a patent by SOLTEC RESEARCH PTY LTD filed on 29 April 1999.

WITNESS my hand this
Fifteenth day of May 2000

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Non-Aqueous Shampoo Composition

Shampoos today are a common household commodity in many communities around the world.

5

The properties of a good shampoo often depend upon the intended application, but may include:

- ability to cleanse hair and scalp thoroughly without stinging or irritation or removing excess natural oils from the scalp.
- 10 - having a cosmetic appeal which imparts lustre, beauty and manageability.

In addition, some shampoos today often have a specialised application, such as minimising eye sting, treating dandruff or other scalp conditions, or generally specific to certain hair types such as dry, oily or permed. These shampoos often contain further additives to meet
15 their specific applications.

The majority of shampoos are in liquid form and contain a large proportion of water. Water is most often used as the bulking agent in shampoos, because of its inert properties, compatibility with other ingredients commonly found in shampoos, its cheap cost, and
20 obvious compatibility to rinse off.

There may be instances where it is desirable to include an additive in a shampoo that may not be compatible with water. In these instances it would be desirable to formulate a commercially and cosmetically acceptable shampoo that contain zero or only a minimal
25 amount of water. That is a non-aqueous shampoo.

However, there are many difficulties in formulating a non-aqueous shampoo where some other non-aqueous bulking agent replaces the water. For example, the use of alcohols in shampoos often reduces or destroys the foam formation which is often desired in shampoo
30 formulations. Alternatively, oils are often too greasy to have an acceptable cosmetic appeal

in the amounts required. In addition, there may be exotic non-aqueous bulking agents that would be prohibitive in a commercially viable shampoo because of the high cost involved.

It is therefore the aim of the present invention to produce a non-aqueous shampoo, which
5 alleviates at least one of the above difficulties.

It has been surprisingly found that replacing an aqueous bulking agent with an organic compound that is soluble in water and miscible with detergents can produce a cosmetically acceptable non-aqueous shampoo.

10 Therefore, in a first aspect of the invention there is provided a non-aqueous shampoo composition which includes an organic compound bulking agent which is soluble in water and miscible with detergents, an additive that would not be compatible in an aqueous based shampoo and at least one detergent.

15 In a further embodiment of the invention, the non-aqueous shampoo composition may include a solvent, a foam booster and/or a mild surfactant.

The organic compound bulking agent may be selected from polyethylene glycol (PEG),
20 monohydric alcohols (examples are alcohols with C₂ to C₆ chain), polyhydric alcohols (examples are propylene glycol, hexylene glycol and glycerol), glycol ethers (examples are pluronic surfactants), ketones (examples are cyclohexanone and diacetone alcohol) and short chained esters (examples are acetates, lactates and carbonates)

25 Organic compounds, which do not inhibit foam formation, are preferred.

Preferably, the organic compound is PEG with a molecular weight of 200 - 800.

In a preferred embodiment, the organic compound is PEG 400. In a further preferred embodiment, the PEG 400 is in an amount of at least 50% based on the total weight of the composition.

5 The detergents of the composition may be selected from alkyl sulphates (examples are sodium lauryl sulphate and ammonium lauryl sulphate), alkyl ether sulphates (examples are sodium laureth sulphate and ammonium laureth sulphate) and sulphsuccinates (example is dialkyl sodium sulfosuccinate).

10 In a preferred embodiment, the detergent is a synthetic detergent and selected from: alkyl sulphates or alkyl ether sulphates.

The foam booster of the composition may be selected from alkyl (amido) betaines (an example is cocamidopropyl betaine), alkanolamides (examples are cocamide DEA and

15 lauramide DEA) and amine oxides (examples are cocamine oxide and lauramine oxide).

The mild surfactant may be any which is commonly used in shampoos. The term "mild" is clearly understood by those skilled in the art and does not require further definition.

20 The shampoo of the current invention includes an additive that would not be compatible in an aqueous based shampoo. The additive may be a compound, which needs to be solubilised in the composition to be effective and/or cosmetically acceptable. The additive may be a pharmaceutical ingredient.

25 Examples of suitable pharmaceutical ingredients include antifungals, antidandruff, antipsoriatic, antipruritic and antibacterials.

Preferably, the pharmaceutical ingredient is the antifungal agent, clotrimazole.

The clotrimazole pharmaceutical ingredient may be present in the shampoo composition in an amount of 0.05 % to 10.00% based on the total weight of the shampoo composition.

5 In a preferred embodiment, the clotrimazole is present in an amount of about 2% based on the total weight of the composition.

In an alternate embodiment of the invention, there is provided a method of topically treating a dermal infection or condition including using the shampoo of the current invention which contains an antifungal agent. In a preferred embodiment, the antifungal agent is
10 clotrimazole.

A solvent in addition to the organic compound bulking agent may be required to achieve solubilisation of the additive. Examples of solvents that may be used are alkyl pyrrolidones (examples are caprylyl pyrrolidone and lauryl pyrrolidone), ketones (examples are
15 cyclohexanone and diacetone alcohol), amines (examples are pyrrole and N-methyl-2-pyrrolidone), esters (examples are acetates, lactates and carbonates), aldehydes, aromatics (and example is alkyl benzene) , monohydric alcohols (examples are alcohols with C₂ to C₆ chain) and polyhydric alcohols (examples are propylene glycol, hexylene glycol and glycerol).

20 The solvent required will depend on the solubility profile of the additive to be incorporated.

In an alternate embodiment of the invention, the non-aqueous shampoo of the current invention may include other agents, including thickening agents such as hydroxypropyl cellulose, carbomers and hectorite clays.

25 In further embodiments of the invention, the shampoo may include a number of additives commonly included in shampoos such as vitamins, essential oils, fruit extracts, dyes or perfumes.

The pH of the shampoo composition may be adjusted to provide the most stable composition. The pH of the final composition may be in the range of 4 – 10, for a clotrimazole shampoo preferably in the basic range of 7 – 9.

- 5 The shampoo composition of the current invention is illustrated by the following example:

Example 1

Ingredient	Class	% W/W
Clotrimazole	Pharmaceutical active	2
Surfadone LP 100	Solvent	10
PEG 400	Organic bulking agent	60.5
Klucel L	Thickening agent	4
Cocamidopropyl Betaine	Surfactant/booster	2.5
Sodium Cocoamphacetate	Mild surfactant	4
Sodium Lauryl Ether Sulfate	Detergent	7
Ammonium Lauryl Sulfate	Detergent	10

- 10 The above ingredients are mixed together to form a clear solution.

It will be appreciated that the invention is in no way limited to the above example.

- 15 The reference to a non-aqueous shampoo composition as herein before described is not intended to exclude compositions that contain a minimum amount of water. A number of ingredients commonly used in shampoos such as surfactants, contain a proportion of water.

Therefore, reference to a non-aqueous shampoo composition is intended to include compositions where no water per se is added to the composition. Alternatively, reference to the non-aqueous shampoo composition is limited to compositions containing no greater than 20%, more preferably no greater than 10% of water based on the total weight of the composition.

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Date: 29 April 1999

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